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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,659	08/10/2001	Einar Stefansson	032904-001	4462

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EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/925,659

Applicant(s)

STEFANSSON, EINAR

Examiner

Zohreh A. Fay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6, 12-26, 31 and 37-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 12-26, 31 and 37-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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Claims 6, 12-26, 31 and 37-51 are presented for examination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 12-26, 31 and 37-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/44603 and Doshi et al.

The WO Patent teaches that of the two macular edema, the one with vascular leakage comprises diabetic retinopathy. See page 2, line 7. The above reference also teaches the use of carbonic anhydrase inhibitors in combination with a hypotensive agent for the treatment of macular edema or any ocular disorder with the etiology of inadequate vascular perfusion. See page 6, lines 20-24 and page 7, line 1. Doshi et al. teach the use of carbonic anhydrase inhibitor for the treatment of macular edema. See column 2, lines 28-37. The primary reference differs from the claimed invention in the use of a carbonic anyhdrase inhibitor per se for the treatment of diabetic retinopathy. It would have been obvious to a person skilled in the art to use carbonic anhydrase inhibitors for the treatment of diabetic retinopathy, considering that macular edema covers diabetic retinopathy as well.

One skilled in the art would have been motivated to combine the teachings of the above references, since one makes clear that macular edema covers diabetic retinopathy and the other relates to the use of carbonic anhydrase inhibitors for the treatment of macular edema. To use a composition being used for the treatment and

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prevention of diabetic retinopathy and use it for slowing the progression of diabetic retinopathy would have been obvious to a person skilled in the art. The substitution of one carbonic anhydrase inhibitor for another is considered to be within the skill of the artisan in the absence of evidence to the contrary. Applicant's arguments and declarations have been carefully considered, but are not deemed to be persuasive. The WO Patent clearly teaches that diabetic retinopathy is one kind of macular edema with vascular leakage. The WO Patent also makes clear that carbonic anhydrase inhibitors have been previously used for the treatment of macular edema and as a result diabetic retinopathy. Doshi et al. also teach the use of carbonic anhydrase inhibitors for the treatment of macular edema. It would have been obvious for a person skilled in the art to use a composition being used for the treatment of macular edema and subsequent diabetic retinopathy and use it for slowing the progression or prevention of macular edema or diabetic retinopathy. The compounds being used for treating a disorder are considered to be useful for prevention or slowing the progression of the same disorder. The use of the term "sole" in certain claims does not overcome the obviousness rejection, considering that such claims also use "comprises", which permits the inclusion of other active ingredients. Furthermore, Doshi et al. use carbonic anhydrase inhibitors without the addition of other active ingredients for the treatment of macular edema.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

